Package leaflet: Information for the patient

Paracetamol/ascorbic acid/pheniramine Norpharm, 500mg/200mg/25mg granules for oral solution

Paracetamol/pheniramine maleate/ascorbic acid

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your pharmacist has told you.

Keep this leaflet. You may need to read it again.

- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet:

1. What Paracetamol/ascorbic acid/pheniramine Norpharm is and what it is used for
2. What you need to know before you take Paracetamol/ascorbic acid/pheniramine Norpharm
3. How to take Paracetamol/ascorbic acid/pheniramine Norpharm
4. Possible side effects
5. How to store Paracetamol/ascorbic acid/pheniramine Norpharm
6. Contents of the pack and other information

1. What Paracetamol/ascorbic acid/pheniramine Norpharm is and what it is used for

The active ingredients are: Paracetamol, Ascorbic acid and Pheniramine maleate
Paracetamol/ascorbic acid/pheniramine Norpharm is used for the short-term relief of stuffy or runny nose (rhinitis), watery eyes and sneezing associated with the symptoms of colds and flu in adults and adolescents aged 15 years and above.

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2. What you need to know before you take Paracetamol/ascorbic acid/pheniramine Norpharm

Do not take Paracetamol/ascorbic acid/pheniramine Norpharm:
- If you are allergic to paracetamol, ascorbic acid or pheniramine maleate or any of the other ingredients of this medicines (listed in section 6);
- If you suffer from glaucoma (increased pressure in the eye);
- If you have problems urinating due to prostate or other problems;
- If you suffer from liver problems;
- If you suffer urinary retention (eg. due to enlargement of the prostate);
- Childer and adolescents below 15 years of age
- If you are taking or have taken in the last 2 weeks monoamine oxidase inhibitors (medicines used to treat depression or Parkinson’s disease).

Warnings and precautions

Talk to your doctor or pharmacist before taking Paracetamol/ascorbic acid/pheniramine Norpharm:
- If you have Gilbert’s syndrome (familial liver disease);
- If you have severe liver or kidney disease;
- If you have haemolytic anemia (due to red blood cells manifested anemia);
- If you suffer from alcoholism;
- If you suffer from malnutrition;
- If you suffer from dehydration;
- If you weigh less than 50 kg;
- If you have abnormal iron metabolism in the body;
- If you have a tendency to form stones in the urinary tract; *(don’t use more than 5 sachets of Paracetamol/ascorbic acid/pheniramine Norpharm per day (i.e. 1 g ascorbic acid per day)).*
- If you are sensitive to acetylsalicylic acid and this causes you bronchospasm (shortness of breath). Paracetamol can also cause this as well;
- If you have haemolytic anaemia;
- If your body lacks the enzyme glucose-6-phosphate dehydrogenase (may cause anemia due to the spontaneous destruction of the red blood cells).

**Children and adolescents**

**Paracetamol/ascorbic acid/pheniramine Norpharm** is intended only for adults and adolescents from 15 years of age.

**Other medicines and Paracetamol/ascorbic acid/pheniramine Norpharm**

Tell your doctor or pharmacist if you are taking, have recently taken any other medication or might take any other medicines.

Do not take in combination with any other medicines containing paracetamol. This is especially important if you are taking or have taken:

- Medicines to treat epilepsy (e.g. phenobarbital, phenytoin or carbamazepine);
- Medicines used to treat tuberculosis (e.g. isoniazid or rifampin);
- Medicines to treat severe pain (e.g. morphine);
- Medicines to relieve pain and inflammation (e.g. ibuprofen or diclofenac);
- Medicines for anxiety or insomnia (e.g. diazepam or zolpidem);
- Medicines to treat psychosis (e.g. chlorpromazine);
- Medicines to treat depression (e.g. imipramine, amitriptyline or St. John’s Wort);
- Medicines to treat Parkinsonism;
- Medicines to treat allergy symptoms such as diphenhydramine;
- Certain medicines for the treatment of hypertension (e.g. clonidine or rilmenidine);
- Medicines used to treat spasms or conditions with disturbances in the bladder or gastrointestinal motility such as propantheline;
- Blood-thinning medicines (e.g. warfarin);
- Baclofen (a medicine used to facilitate strong muscle spasms);
- Thalidomide (a medicine used in multiple myeloma - bone marrow cancer);
- Disopyramide (a medicine used to treat abnormal heart rhythms);
- Probenecid (a medicine used to treat gout);
- Cholestyramine (a medicine used to lower blood cholesterol);
- Chloramphenicol (a medicine used for certain bacterial infections);
- Zidovudine (a medicine used to treat HIV infection).

**Paracetamol/ascorbic acid/pheniramine Norpharm with food, drink or alcohol.**

Avoid alcohol whilst taking this medicine.

**Pregnancy, breast-feeding and fertility**

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. It is not recommended for pregnant or breast feeding women.

**Driving and using machines**

The possibility of drowsiness or reduced alertness should be taken into consideration whilst taking this medicine. If affected, do not drive or operate machinery.

**Paracetamol/ascorbic acid/pheniramine Norpharm contains sucrose:**
Each sachet contains 11.555 g of sucrose: patients with diabetes mellitus should consider this before taking this medicine. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Paracetamol/ascorbic acid/pheniramine Norpharm

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and adolescents over 15 years of age:
The recommended dose is 1 sachet 2 or 3 times a day, if necessary, you can be take up to 6 sachets per day, but there should be at least a 4 hour interval between intakes. The maximum daily dose is 6 sachets (3 g paracetamol). Add the contents of the sachet into a glass of warm or cold water, stir until the granules dissolve, and drink immediately.

Patients with hepatic impairment:
Patients with impaired hepatic function should take Paracetamol/ascorbic acid/pheniramine Norpharm with caution. If you drink alcohol excessively, the maximum daily dose is 4 sachets (2 g paracetamol). You should take this medicine every 8 hours. If you suffer from severe hepatic impairment or active liver disease, then you should not take Paracetamol/ascorbic acid/pheniramine Norpharm.

Patients with renal impairment:
If you suffer from severe renal function (creatinine clearance below 10ml/min), this medicine should be taken every 8 hours.

Children and adolescents below 15 years:
Children and adolescents below 15 years should not use Paracetamol/ascorbic acid/pheniramine Norpharm due to absence of sufficient data in this population.

This medicine should not be taken for more than 3 days.

If you take more Paracetamol/ascorbic acid/pheniramine Norpharm than you should
If you have taken more Paracetamol/ascorbic acid/pheniramine Norpharm than you should; stop treatment and contact your doctor immediately, even if you feel well, because of the risk of delayed, serious liver damage.

If you forget to take Paracetamol/ascorbic acid/pheniramine Norpharm
Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Tell your doctor immediately if you notice or feel any of the following:
• swollen face, tongue, or throat;
• fainting;
• difficulty breathing or swallowing.

The following side effects have been reported:

Rare (may affect up to 1 in 1,000 people)
• Allergic reactions: skin rash, hives, itching, redness, small red spots on the face, tongue or throat, difficulty breathing or swallowing, fainting, anaphylactic shock.
Very rare (may affect up to 1 in 10,000 people)
• reduced number of red blood cells, white blood cells or platelets.
• serious skin reactions

Not known (can not be estimated from the available data)
• constipation;
• agitation, anxiety, insomnia, confusion or hallucinations (seeing or hearing or smell things that are not);
• memory and attention disorders, particularly in the elderly;
• dizziness (vertigo), tremor;
• disorders of balance or coordination;
• Blurred vision, mydriasis;
• dizziness or fainting when standing up from a sitting or lying position;
• urinary retention.

If you experience any side effects, including those that are not listed above, please tell your doctor or pharmacist.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Paracetamol/ascorbic acid/pheniramine Norpharm

Keep this medicine out of the sight and reach of children

Do not use this medicine after the expiry date that is printed on the carton.

Store above 30C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Paracetamol/ascorbic acid/pheniramine Norpharm contains:

The active substances are: Paracetamol 500mg, Ascorbic acid 200mg and Pheniramine maleate 25mg
The other ingredients are: Sucrose, Carribbean flavour containing (lemon oil, sweet orange oil, orange pulp, rum extract, vanillin, maltol, citron, gamma lactons, citric acid (E330), maltodextrin, acacia, sucrose). Anhydrous citric acid, Acacia, spray dried Saccharin sodium

What Paracetamol/ascorbic acid/pheniramine Norpharm looks like and contents of the pack
<Product name> is packed in paper/Al/PE sachets. Each sachet contains a white to slightly yellow powder with a characteristic odour of citrus fruit and rum

Boxes containing

6, 8 sachets

Not all pack sizes may be marketed.
Marketing Authorisation Holder
Norpharm Regulatory Services,
26 Laurence Street, Drogheda,
Co. Louth, Ireland

Manufacturer
Farmea, 10, rue Bouche Thomas ZAC d’Orgemont 4900 Angers, France

This medicinal product is authorised in the Member States of the EEA under the following names:

This leaflet was last revised in: